4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA-2019-D-4212]

Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product--Compliance Policies, Revision 1; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled "Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product--Compliance Policies, Revision 1." This revised guidance explains that FDA intends to extend for an additional year (from November 27, 2023, to November 27, 2024), the enforcement policies described in the guidance entitled "Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product-Compliance Policies," published in the *Federal Register* on October 23, 2020 (the 2020 Compliance Policies). The 2020 Compliance Policies relate to provisions in the Federal Food, Drug, and Cosmetic Act (FD&C Act), as added by the Drug Supply Chain Security Act (DSCSA), requiring wholesale distributors to verify the product identifier prior to further distributing saleable returned product and requiring dispensers to verify the product identifier for suspect or illegitimate product in the dispenser's possession or control.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-D-4212 for "Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product--Compliance Policies." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sarah Venti, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3130, drugtrackandtrace@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On October 23, 2020, FDA published the 2020 Compliance Policies. FDA is announcing the availability of a guidance for industry entitled "Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product--Compliance Policies, Revision 1", which extends the enforcement policies described in the 2020 Compliance Policies for an additional year, from November 27, 2023, until November 27, 2024. As described in this revised guidance, FDA does not intend to take enforcement action, prior to November 27, 2024, against wholesale distributors who do not verify the product identifier prior to further distributing saleable returned product, or against dispensers who do not verify the product identifier of the statutorily designated proportion of suspect or illegitimate product in the dispenser's possession or control,

as required under section 582 of the FD&C Act (21 U.S.C. 360eee-1), as added by the DSCSA (Title II of Pub. L. 113-54).

This revised guidance is being issued consistent with FDA's good guidance practices regulations (21 CFR 10.115). FDA is implementing this guidance without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). FDA made this determination because this guidance document provides information pertaining to statutory requirements that FDA had planned to begin enforcing as of November 27, 2023, for wholesale distributors to verify the product identifier prior to further distributing saleable returned product under section 582(c)(4)(D) of the FD&C Act and for dispensers to verify the product identifier, including the standardized numerical identifier, for suspect or illegitimate product in the dispenser's possession or control under section 582(d)(4)(A)(ii)(II) and (d)(4)(B)(iii) of the FD&C Act. It is important that FDA provide this information before that date. Although this guidance document is being implemented immediately, it remains subject to comment in accordance with the Agency's good guidance practices (21 CFR 10.115(g)(3)).

Beginning November 27, 2019, wholesale distributors were required, under section 582(c)(4)(D) of the FD&C Act, to verify the product identifier, including the standardized numerical identifier, on each sealed homogeneous case of saleable returned product, or, if such product is not in a sealed homogeneous case, on each package of saleable returned product, prior to further distributing such returned product. In the *Federal Register* published September 24, 2019 (84 FR 50044), FDA issued a notice announcing the availability of the Wholesale Distributor Verification Requirement for Saleable Returned Drug Product--Compliance Policy guidance (2019 Compliance Policy), which described a 1-year enforcement policy with respect to this wholesale distributor requirement, until November 27, 2020. The Agency subsequently published the 2020 Compliance Policies, which extended the enforcement policy in the 2019 Compliance Policy with respect to this wholesale distributor requirement for 3 years, until

November 27, 2023, and also included an enforcement policy until that same date with respect to the requirement for dispensers to verify the product identifier, including the standardized numerical identifier, for suspect or illegitimate product in the dispenser's possession or control.

Since the announcement of the 2020 Compliance Policies, FDA has received additional comments and feedback from wholesale distributors, as well as other trading partners and stakeholders, expressing concern with industry-wide readiness for implementation of the verification of saleable returned product requirement for wholesale distributors and the challenges stakeholders face with developing interoperable, electronic systems to enable such verification and achieve interoperability between networks. Specifically, comments received point out continuing challenges posed by the large volume of saleable returned product, explaining that wholesale distributors still need more time to test verification systems using real-time volumes of saleable returned product with all trading partners involved, as opposed to using small-scale pilot test projects. Given all these concerns, FDA recognizes that some wholesale distributors may need additional time, beyond November 27, 2023, before they can begin verifying returned products prior to resale or other further distribution as required by section 582(c)(4)(D) of the FD&C Act in an efficient, secure, and timely manner. Additionally, section 582 of the FD&C Act requires certain trading partners (manufacturers, repackagers, wholesale distributors, and dispensers) to exchange transaction information, transaction history, and a transaction statement when engaging in transactions involving certain prescription drugs. Section 581(27)(E) of the FD&C Act (21 U.S.C. 360eee(27)(E)) requires that the transaction statement include a statement that the entity transferring ownership in a transaction had systems and processes in place to comply with verification requirements under section 582 of the FD&C Act. This revised guidance also explains that, prior to November 27, 2024, FDA does not intend to take action against a wholesale distributor for providing a transaction statement to a subsequent purchaser of product on the basis that such wholesale distributor does not yet have systems and processes in place to comply with the saleable return verification requirements

under section 582(c)(4)(D) of the FD&C Act. The guidance explains the scope of the compliance policy in further detail.

In addition to helping minimize possible disruptions in the distribution of certain prescription drugs in the United States, FDA believes that by extending the enforcement approach described in the 2020 Compliance Policies until November 27, 2024, wholesale distributors will be able to focus resources and efforts on the requirements for enhanced drug distribution security under section 582(g) of the FD&C Act (as described below). Thus, instead of developing separate processes or infrastructures solely for the saleable return verification requirement, wholesale distributors can incorporate the saleable return verification requirements into the enhanced verification required under section 582(g) of the FD&C Act.

Further, section 582 of the FD&C Act, as added by the DSCSA, also established the requirements that specify how dispensers must investigate suspect and illegitimate product. As part of the investigation, section 582(d)(4)(A)(ii)(II) of the FD&C Act requires dispensers to verify the product identifier, including the standardized numerical identifier, of at least three packages or 10 percent of such suspect product, whichever is greater, or all packages, if there are fewer than three, corresponds with the product identifier for such product in the dispenser's possession or control. Section 582(d)(4)(B)(iii) of the FD&C Act requires dispensers to verify product as described in section 582(d)(4)(A)(ii), which includes the section 582(d)(4)(A)(ii)(II) requirement, in response to a notification from FDA or a trading partner that the product is an illegitimate product.

In response to comments received from stakeholders regarding dispenser readiness to meet these requirements, and to minimize possible disruptions in the distribution of affected prescription drugs in the United States, this guidance also announces that FDA does not intend to take action before November 27, 2024, against dispensers who do not verify the product identifier of the statutorily designated proportion of suspect product as required by section 582(d)(4)(A)(ii)(II) of the FD&C Act, and that part of section 582(d)(4)(B)(iii) of the FD&C Act

that requires dispensers to perform the same verification activities of section 582(d)(4)(A)(ii)(II) when responding to a notification of illegitimate product from FDA or another trading partner. FDA believes that the 1-year extension under this guidance of the applicable 2020 Compliance Policies will facilitate the ability of dispensers to ensure the systems and processes that are put into place to meet the enhanced drug distribution security requirements, which FDA will generally not enforce before November 27, 2024, will also fulfill the dispenser verification requirements under section 582(d)(4) of the FD&C Act.

In the "Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act--Compliance Policies" (Enhanced Drug Distribution Security Compliance Policies) (88 FR 58498), FDA announced a 1-year enforcement policy with respect to the enhanced drug distribution security requirements set to take effect on November 27, 2023. FDA chose to adopt this enforcement policy until November 27, 2024, because FDA was aware that some stakeholders were facing challenges with implementing the section 582(g) requirements and needed additional time to comply with these requirements.

While FDA generally expects trading partners to have the systems and processes in place to meet the requirements of section 582(g) of the FD&C Act, FDA recognizes that some technical and operational issues may not be fully resolved by November 27, 2023. The Agency believes the Enhanced Drug Distribution Security Compliance Policies can help trading partners address such issues by accommodating the additional time that may be needed to implement, troubleshoot, and mature their systems and processes. For additional information about enhanced drug distribution security please see the June 2021 draft guidance for industry entitled "Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act" (available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhanced-drug-distribution-security-package-level-under-drug-supply-chain-security-act).

This guidance represents the current thinking of FDA on "Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product--Compliance Policies." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.[1]

II. Paperwork Reduction Act of 1995

FDA concludes that this guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov.

Dated: August 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-18899 Filed: 8/31/2023 8:45 am; Publication Date: 9/1/2023]

[1] The Office of the Federal Register has published this document under the category "Rules and Regulations" pursuant to its interpretation of 1 CFR 5.9(b). We note that the categorization as such for purposes of publication in the *Federal Register* does not affect the content or intent of the document. See 1 CFR 5.1(c).